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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/037,460	03/10/98	HASTINGS G	325800-626(P

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EXAMINER	
SAOUD, C	
ART UNIT	**PAPER NUMBER**
1646	20

DATE MAILED: 04/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/037,460	Applicant(s) HASTINGS et al.
	Examiner Christine Saoud	Group Art Unit 1646

☒ Responsive to communication(s) filed on *Mar 27, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *54-67, 75-92, 102-107, and 115-175* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *54-67, 75-92, 102-107, and 115-175* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 27 March 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/037,460 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendment

2. Claims 108-112 have been canceled and claims 115-175 have been added as requested in the amendment of paper #19, filed 27 March 2000. Claims 54-67, 75-92, 102-107, and 115-175 are pending in the instant application.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed 27 March 2000 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 54-67, 75-92, 102-107, and 115-175 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant specification that the vascular IBP-like growth factor described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the

court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the vascular IBP-like growth factor (VIGF) of the instant application can be used for wound healing and associated therapies, for enhancement of growth of vascular smooth muscle and endothelial cells, and therapeutically in ischemic tissues and for coronary stenosis (see page 19 of the specification). Until some actual and specific significance can be attributed to the protein identified in the specification as VIGF, or the gene encoding it, the instant invention is incomplete. The DNA of the instant invention and the protein encoded thereby are compounds which share some structural similarity to connective tissue growth factor and to the CCN family of proteins based on sequence similarity. The CCN family of proteins includes connective tissue growth factor, CEF-10, CYR-61, FISP-12 and NOV. These proteins share several common structural motifs, including a consensus sequence found in insulin-like growth factor binding proteins. Proteins of this family are thought to be stimulators of cell

proliferation and or transformation, but there does not appear to be a common function shared by all of the family members. It is not clear if the protein of the instant application would be a growth factor, and inhibitor of cell proliferation, a binding protein, or even possibly a transcription factor based on its structure alone. In the absence of a knowledge of the receptor to which VIGF binds, or the biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for VIGF then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

8. Claims 54-67, 75-92, 102-107, and 115-175 are rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. §101.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 115-117, 119-175 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

First, the claims are directed to subject matter which is new matter. The instant claims include the limitation of a nucleic acid encoding amino acids 30-44 of SEQ ID NO:2 and amino acids 55-69 of SEQ ID NO:2. Applicant points to page 6, lines 5-6 for support for these claim limitations. However, this portion of the specification only indicates that these are domains in the disclosed protein, and does not provide a basis for a claim to a nucleic acid comprising a nucleic acid encoding only these domains, absent evidence to the contrary.

Second, the claims are directed to nucleic acids which hybridize to SEQ ID NO:1 or to the cDNA contained in ATCC Deposit No. 75874 under stringent conditions recited in the claims as well as nucleic acids which have a particular percentage if sequence identity to the disclosed sequence. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO:2. This nucleic acid molecule has a nucleic acid sequence of SEQ ID NO:1 and is contained in ATCC Deposit No. 75874. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. First, the claims are not limited to polynucleotide molecules encoding a protein with a specific amino acid sequence. The claims only require the nucleic acid molecule to hybridize to a disclosed sequence or have a

percentage of sequence identity to the disclosed sequence. The specification only describes a single nucleic acid encoding a polypeptide from a human and fails to teach or describe any other nucleic acid which would meet the limitations of the claims. The breadth of the claims is such that the claims encompass polynucleotides from other species and polynucleotides which encode variant polypeptides as well as nucleic acids which do not encode polypeptides. There is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art. Additionally, the specification fails to provide a function for the disclosed polypeptide, and therefore, nucleic acid.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the nucleic acid of SEQ ID NO:1. The specification does not provide a complete structure of those polynucleotides which encode a polypeptide as described in the claims and hybridize to the recited sequence under the recited stringency conditions of the claims or which have the percentage of sequence identity recited in the claims. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between

function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those polynucleotides which hybridize to SEQ ID NO:1 under the recited stringency conditions or which have the degree of sequence identity recited in the claims) because the claims encompasses different species and variants and the specification teaches one embodiment. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that the claims also are directed to nucleic acid molecules comprising contiguous portions of SEQ ID NO:1. These claims encompass genomic DNA, for which the instant specification fails to provide a written description. Therefore, these claims are also directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Double Patenting

11. Claims 115, 120-122, 135-149, 162-175 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 08/196,362 (SEQ ID NO:7788 and 7775), 08/346,731 (SEQ ID

NO:552), 08/420,856 (SEQ ID NO:552), 08/221,623 (SEQ ID NO:114), and 08/276,163 (SEQ ID NO:15161) for the reasons of record in paper #8 as originally applied to claims 93-100, 108, and 111-112. Applicant has requested that this ground of rejection be held in abeyance, however, it would not be proper to withdraw this ground of rejection at this time while there is common subject matter between the pending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

12. Claims 115, 120-122, 135-149, 162-175 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 08/196,362 (SEQ ID NO:7788 and 7775), 08/346,731 (SEQ ID NO:552), 08/420,856 (SEQ ID NO:552), 08/221,623 (SEQ ID NO:114), and 08/276,163 (SEQ ID NO:15161) which have a common assignee with the instant application for the reasons of record in paper #8 as originally applied to claims 93-100, 108 and 111-112.

Applicant has requested that this rejection be held in abeyance until indication of allowable subject matter, however, it would not be proper to withdraw this ground of rejection at this time while there is common subject matter between the pending applications.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 25, 2000

CHRISTINE SAOUD
PATENT EXAMINER

Christine Saoud